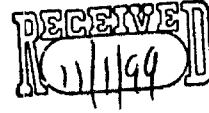




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October 26, 1999

The Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. Street S.W.
Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Diaplex is formulated to support the healthy function of the pancreas and the metabolism of carbohydrates and fats.
- (2) Chromium is an essential trace mineral that helps to maintain normal levels of blood sugar and fat in the body.
- (3) Diaplex contains chromium, the primary component of the Glucose Tolerance Factor (GTF) and the biologically active form of chromium that supports the action of the insulin formed naturally by the body.

These statements are made for a dietary supplement containing a proprietary blend of betaine hydrochloride, bovine pancreas PMG™ extract, alfalfa, calcium lactate, buckwheat juice (whole plant), buckwheat (seed), pea (vine) juice, carrot (root), oat flour, beet (leaf) juice, bovine pancreas Cytosol™ extract, bovine liver, bovine spleen Cytosol™ extract, ammonium chloride, defatted soy (bean), pancreatin (3X), beet (root), pepsin (1:10,000), bovine pituitary PMG™ extract, bovine kidney, bovine prostate, inositol, enzymatically processed *Tillandsia usneoides* and beet (root), bovine orchic extract, l-cysteine hydrochloride, bovine adrenal Cytosol™ extract, bovine liver fat extract, and flaxseed oil extract. Other ingredients include gelatin, chromium yeast, magnesium citrate, water, lactose, cellulose, potassium bicarbonate, fatty acids, natural colors, vitamin A palmitate, niacinamide, ascorbic acid, pyridoxal-5-phosphate, and prolamine iodine (zein). And the name of the product is Diaplex®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden
Standard Process Inc.

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